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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,056	10/13/1999	ROGER CAROLUS AUGUSTA EMBRECHTS	JAB-1267	6783
7590 03/11/2004			EXAMINER	
PHILIP S. JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			KISHORE, GOLLAMUDI S	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/403,056

Applicant(s)

EMBRECHTS ET AL.

Examiner

Gollamudi S Kishore, PhD

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15 and 17-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-15 and 17-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1-8-04 1-2.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

RCE dated 1-8-04 is acknowledged.

Claims included in the prosecution are 1, 3-15 and 17-23.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1, 3-15 and 17-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

According to independent claims 1, 3 and 6, x represents either 1, 2 or 3 and $x+y=3$. First of all, it is unclear as to what number y has. Secondly, if x is 3, does that mean y is zero meaning that there is no (O-Na)? How is this possible?
Clarification is requested.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1, 3-15 and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Liu (5,458,851) or Mason (5,537,742) each in combination with Mayhew (4,209,449), Fost (5,286,719) by themselves or in combination.

Liu discloses shampoo formulations containing the various additives and ketoconazole as the active ingredient; Liu also discloses that ketoconazole is an anti-fungal

agent and is useful for the treatment of psoriasis and seborrheic dermatitis (note the abstract, columns 1-4, Examples and claims).

Mason similarly discloses shampoo preparations containing ketoconazole, econazole or miconazole for the treatment of seborrhea. Mason notes the association of this disease with yeast (fungus) (note the abstract, columns 1-2 and claims).

What is lacking in the above references is the inclusion of instant phospholipid in the shampoo preparations.

Mayhew while disclosing shampoos, teaches that instant phospholipid exhibit outstanding foaming, viscosity-building, wetting, cleaning, bacteriostatic and other properties (note the abstract, col. 1, line 5 through col. 2, line 8, col. 3, line 53 through col. 5, line 56 and Examples 1-4 in particular).

Fost teaches that instant synthetic phospholipids unexpectedly exhibit excellent antifungal activity and could be used in combination with various surfactants in personal care products (abstract, col. 2, line 5 through col. 4, line 64).

The inclusion of the phospholipids taught by Mayhew and/or Fost in the shampoo compositions of Liu or Mason would have been obvious to one of ordinary skill in the art since Mayhew clearly teaches the excellent properties of these phospholipids and Fost teaches the excellent antifungal activity of these phospholipids and advocates their use in personal care products. In essence, one would be motivated to combine the phospholipid for not only the excellent properties, but also its anti-fungal activity.

Art Unit: 1615

Claims 1, 3-15 and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Liu (5,456,851) or Mason (5,536,742) each in combination with Mayhew (4,209,449) or Fost (5,648,348) by themselves or in combination as set forth above, in further in combination with GB 22 56 139.

The teachings of Liu, Mason, Mayhew and Fost have been discussed above. What is lacking in these references is the combination of the anti-fungal agent and a phospholipid.

GB while disclosing emulsions containing terbinafine and phospholipids, teaches that such a combination results in enhanced efficacy of the compound (note the abstract, page 2, 4 and examples; example 3 in particular).

One of ordinary skill in the art would be motivated further to use phospholipid taught by Mayhew or Fost together with the antifungal compounds of either Liu or Mason, in view of the enhanced efficacy of antifungal agents by phospholipids taught by GB.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Application/Control Number: 09/403,056

Page 5

Art Unit: 1615

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1234.


Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK